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53 State St	reet			ART UNIT	PAPER NUMBER
Boston, MA 02109				1641	

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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		Application No.	Applicant(s)				
Office Action Summary		09/977,358	PIEPER ET AL.				
	Office Action Summary	Examiner	Art Unit				
	T. 1111 NO DATE CH.	David J Venci	1641				
Period fo	The MAILING DATE of this communication ap or Reply	pears on the cover sheet with the o	correspondence address				
THE - Exte after - If the - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1. SIX (6) MONTHS from the mailing date of this communication. p period for reply specified above is less than thirty (30) days, a rep operiod for reply is specified above, the maximum statutory period are to reply within the set or extended period for reply will, by statut reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however, may a reply be tirely within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from e. cause the application to become ABANDONE	mely filed ys will be considered timely. the mailing date of this communication. TD (35 U.S.C. & 133)				
Status							
1)🛛	Responsive to communication(s) filed on <u>07 S</u>	September 2004.					
		s action is non-final.					
3)□	· ·						
Dispositi	ion of Claims						
5)□ 6)⊠ 7)□	Claim(s) <u>1-44</u> is/are pending in the application 4a) Of the above claim(s) <u>1-26 and 43</u> is/are w Claim(s) is/are allowed. Claim(s) <u>27-42 and 44</u> is/are rejected. Claim(s) is/are objected to. Claim(s) <u>1-44</u> are subject to restriction and/or	rithdrawn from consideration.					
Applicati	on Papers						
9)	The specification is objected to by the Examine	er.					
10)	☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
	Applicant may not request that any objection to the	- · ·	` <i>'</i>				
11)[\]	Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex		· · · · · · · · · · · · · · · · · · ·				
	ınder 35 U.S.C. § 119						
12)[] a)[Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Burea see the attached detailed Office action for a list	ts have been received. Is have been received in Applicati rity documents have been receive u (PCT Rule 17.2(a)).	ion No ed in this National Stage				
Attachmen	t(s)						
	e of References Cited (PTO-892)	4) Interview Summary					
3) 🔀 Inforn	e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date	Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ate Patent Application (PTO-152)				

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to an affinity binding composition, classified in class 435, subclass 7.8, for example.
- II. Claims 1, 2 and 9, drawn to an affinity column comprising a third receptor, classified in class 435, subclass 288.6, for example.
- III. Claims 1, 6 and 10-11, drawn to an affinity column comprising an antibody, classified in class 435, subclass 7.1, for example.
- IV. Claims 1, 7 and 12, drawn to an affinity column comprising a porous matrix, classified in class 210, subclass 656, for example.
- V. Claims 1 and 8, drawn to an affinity column, classified in class 422, subclass 70, for example.
- VI. Claim 13, drawn to an apparatus, classified in class 435, subclass 287.1.
- VII. Claims 14-21, drawn to a method for preparing a receptor matrix, classified in class 436, subclass 535, for example.
- VIII. Claims 22-23, drawn to an apparatus, classified in class 435, subclass 287.2, for example.
- IX. Claim 24, drawn to a method for preparing a receptor matrix, classified in class 436, subclass 523, for example.
- X. Claims 25-26, drawn to a method for forming a covalent bond between two proteins, classified in class 436, subclass 532, for example.
- XI. Claims 27-42 and 44 drawn to a method for separating ligands, classified in class 436, subclass 501, for example.
- XII. Claim 43, drawn to an electrophoresis gel, classified in class 210, subclass 658, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as subcombination and combination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because a chamber having an inlet and outlet has separate patentable utility as a centrifugal filtration device, for example. The subcombination of Invention I has separate utility such as a therapeutic delivery composition. This same relationship also applies to Inventions I-III, I-IV, I-V, I-VI, and I-VIII.

Inventions I and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process of Invention VII can be used to make another materially different product, such as a therapeutic delivery composition. This same relationship also applies to Inventions VII-II, VII-III, VII-IV, VII-V, VII-VI, and VII-VIII.

Inventions I and IX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process of Invention IX can be used to make another materially different product, such as a

therapeutic delivery composition. This same relationship also applies to Inventions IX-II, IX-III, IX-IV, IX-V, IX –VI and IX-VIII.

Inventions I and X are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process of Invention X can be used to make another materially different product, such as a therapeutic delivery composition. This same relationship also applies to Inventions X-II, X-III, X-IV, X-V, X-VI and X-VIII.

Inventions I and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process of Invention XI can be practiced with a materially different product, such as an ion exchange composition. This same relationship also applies to Inventions XI-II, XI-III, XI-IV, XI-V, XI-VI, XI-VIII, and XI-XII.

Inventions (I, II, III, IV, V, VI, VII; VIII, or IX) and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because

Inventions (I, II, III, IV, V, VI, VII, VIII, or IX) require a receptor, while Invention XII requires an electrophoresis gel.

Inventions X and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention X requires a crosslinking agent, while Invention XII requires an electrophoresis gel.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention II requires a third receptor, while Invention III requires antibodies.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention II requires a third receptor, while Invention IV requires a porous matrix.

Inventions II and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the

subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant

case, the combination as claimed does not require the particulars of the subcombination as

claimed because a third receptor immobilized on a solid phase matrix has separate patentable

utility as a affinity binding composition, for example. The subcombination of Invention V has

separate utility such as a centrifugal filtration device.

Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not

disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the

different inventions have different modes of operations because Invention II requires a third

receptor, while Invention VI requires a conduit.

Inventions II and VIII are unrelated. Inventions are unrelated if it can be shown that they are not

disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the

different inventions have different modes of operations because Invention II requires a third

receptor, while Invention VI requires a fluid connection.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not

disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the

different inventions have different modes of operations because Invention III requires an

antibody, while Invention IV requires a porous matrix.

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Inventions III and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because an antibody receptor has separate patentable utility as a affinity binding composition, for example. The subcombination of Invention V has separate utility such as a centrifugal filtration device.

Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention III requires an antibody, while Invention VI requires a conduit.

Inventions III and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention III requires an antibody, while Invention VIII requires a fluid connection.

Inventions IV and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the

subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because a porous matrix has separate patentable utility as an affinity binding composition, for example. The subcombination of Invention V has separate utility such as a

centrifugal filtration device.

Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention IV requires a porous matrix, while Invention VI requires a conduit.

Inventions IV and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention IV requires a porous matrix, while Invention VIII requires a fluid connection.

Inventions V and VI are related as subcombination and combination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because a conduit or fluid connection have separate patentable utility as an in-line

switching valve, for example. The subcombination has separate utility such as a centrifugal filtration device. This same relationship also applies to Inventions V-VIII.

Inventions VI and VIII are related as subcombination and combination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because an immobilized ligand has separate patentable utility as a fluorescent probe, for example. The subcombination has separate utility such as a centrifugal filtration device.

Inventions VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention IX requires a second receptor matrix and Invention VII requires a receptor containing liquid.

Inventions VII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention VII requires the step of eluting, while Invention X requires a crosslinking agent.

Inventions IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention IX requires a matrix, while Invention X requires a crosslinking agent.

Inventions XI and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention XI requires the step of removing ligands, while Invention X requires a crosslinking agent.

Inventions VII and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention VII requires the step of eluting, while Invention XI requires the step of analysis of remaining ligands.

Inventions IX and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention IX requires the step of mixing matrices, while Invention XI requires the step of analysis of remaining ligands.

Inventions X and XI are unrelated. Inventions are unrelated if it can be shown that they are not

disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the

different inventions have different modes of operations because Invention X requires a

crosslinking agent, while Invention XI requires the step of analysis of remaining ligands.

Because these inventions are distinct for the reasons given above and the search required for

each is not required for the others, restriction for examination purposes as indicated is proper.

Applicant's election of Invention XI, claims 27-42 and 44, without traverse in the reply filed on

09/07/04 is acknowledged. Claims 1-26 and 43 are withdrawn from further consideration

pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no

allowable generic or linking claim.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37

CFR 1.67(a) identifying this application by application number and filing date is required. See

MPEP §§ 602.01 and 602.02. The oath or declaration is defective because:

It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR

1.76.

It does not identify the U.S. provisional application on which priority is claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly

claiming the subject matter which the applicant regards as his invention.

Claims 27-42 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite

for failing to particularly point out and distinctly claim the subject matter which applicant regards

as the invention.

In claim 27, the claim preamble does not correspond to the method outcome. For example, the

preamble recites a method for separating ligands from a sample. However, the final method

step recites the step of analyzing the remaining ligands. It is not clear from the claim language

whether the purpose of the method is to separate ligands or analyze ligands.

In claims 35-38, the recitation of "the process" lacks antecedent basis.

In claims 35 and 37, the recitations of "the receptors" and "the same receptors" lack antecedent

bases.

In claims 41-42, the recitation of "division" is indefinite. A person of ordinary skill in the art

cannot ascertain the standard or degree of "division" because it is not clear whether "division" is

based on a numerical division and/or a functional and/or structural "division."

In claim 44, the recitation of "modified ligand-containing sample" lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-42 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Wheatley, 603 J. CHROMATOGR. 273 (1992).

Wheatley describes a method for separating ligands (see Abstract, "albumin and transferrin") for analysis of remaining ligands (see Fig. 3(b), "IgG") comprising: removing at least two specific predefined ligands (see p. 275, col. 2, Chromatography, "transferrin, albumin") and analyzing the remaining ligands (see Fig. 3(b), "IgG").

With respect to claim 30, Wheatley describes a method for separating ligands wherein the ligands are proteins (see Abstract, "albumin and transferrin").

With respect to claim 31, Wheatley describes a method for separating ligands wherein the ligands are removed by predefined receptors (see p. 274, col. 2, Purification of Anti-Albumin and Anti-Transferrin antibodies from Goat Antiserum) that are in insoluble form (see p. 275, col. 2, Preparation of the Multiple Ligand Affinity Column: Immobilization of Anti-Transferrin and Anti-Albumin Antibodies).

With respect to claims 32-33, Wheatley describes a method for separating ligands wherein at least 50% or 75% by weight of all ligands are removed (see p. 275, col. 2, "The capacity of the affinity cartridges was measured and found to be 330 μ g and 375 μ g, respectively, for transferrin and albumin") (see Fig. 2(b), noting that 13.3 μ g was loaded onto the column, noting absence of peaks).

With respect to claim 34, Wheatley describes a method for separating ligands wherein the bound ligands are removed from the receptor (see p. 275, col. 2, CHROMATOGRAPHY, "the proteins were eluted using a linear salt gradient").

With respect to claim 35, Wheatley describes a method for separating ligands wherein the receptors are reused (see p. 275, col. 2, CHROMATOGRAPHY, "The chromatographic conditions... were identical for all injections").

With respect to claim 39, Wheatley describes a method for separating ligands wherein the remaining ligands are separated and quantified (see Fig. 3(b), "IgG", noting area under peak).

With respect to claim 44, Wheatley describes a modified ligand-containing sample (see Fig. 3(b), the "modified" sample is the column eluate in Fig. 3(b)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 28-29 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wheatley, 603 J. CHROMATOGR. 273 (1992) in view of Lackie (US 5,372,783).

Wheatley describes a method for separating ligands as substantially described supra.

Wheatley does not teach a method wherein at least three or four ligands are removed. Wheatley does not teach a method wherein at least one receptor (or receptor division) is selectively removable from another receptor. Wheatley does not teach a method wherein at least two divisions of receptors are immobilized in two different predefined locations.

However, Lackie teaches a chromatography column wherein at least three or four ligands are removed (see col. 6, lines 54-56, "one may provide a plurality of bead masses, each coated with a different ligand"). Lackie also teaches a chromatography column wherein at least one receptor (or receptor division) is selectively removable from another receptor (see col. 6, lines 49-54, "can be punched to produce the desired cylinders for insertion into tubes 42A"). Finally, Lackie also teaches a chromatography column wherein at least two divisions of receptors are immobilized in two different predefined locations (see Fig. 7) (see col. 6, lines 54-56, "one may provide a plurality of bead masses, each coated with a different ligand").

Therefore, it would have been obvious for a person of ordinary skill in the art to have provided a method for separating ligands, as taught by Wheatley, with the modified chromatography column of Lackie because Lackie teaches that his chromatography column has the ability to incorporate several different receptors in order to simultaneously assay several different ligands (see col. 6, lines 56-60). The ability to simultaneously assay several different ligands is important because Wheatley suggests that his method for separating ligands can be extended beyond a simple two protein extraction to also assay multi-component contaminant mixtures (see p. 277, col. 2, lines 7-11).

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 27-42 and 44 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 27-42 and 44 of copending Application No. 10/250,898. This is a

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provisional double patenting rejection since the conflicting claims have not in fact been

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patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should

be directed to David J Venci whose telephone number is 571-272-2879. The examiner can

normally be reached on 08:00 - 16:30 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor,

Long Le can be reached on 571-272-0823. The fax phone number for the organization where

this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application

Information Retrieval (PAIR) system. Status information for published applications may be

obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci Examiner Art Unit 1641

djv

LONG V. LE SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600

7/1/64